



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 1999

Harry Wallner, Director
Mercy Wellness Center
5 12 Main Street
Williston, North Dakota 58801

Re: Docket No. 99P-4132

Dear Mr. Wallner:

This responds to your citizen petition dated August 4, 1999, in which Mercy Wellness Center requests an exemption or variance from compliance with the Performance Standard for Electrode Lead Wires and Patient Cables. Your request is for the medical devices identified on the enclosed list, which you provided with your letter.

Your petition states that you were not successful in finding "inexpensive adapters" or "retrofit" for these medical devices. Consequently, they do not meet the Performance Standard for Electrode Lead Wires and Patient Cables. Your petition also states that the number of rural satellite offices you service complicates the situation.

At this time, I cannot grant a permanent exemption from the Performance Standard for Electrode Lead Wires and Patient Cables for the medical devices listed above. However, I am granting a temporary variance from this standard until May 11, 2001. During this time period, the Food and Drug Administration will continue to seek resolution to the issue of the apparent lack of adapters that would bring electrode lead wires and patient cables into compliance with the performance standard.

I trust that this response fully addresses your concerns. If additional information is required, please contact Kent Berthold in our Office of Compliance at (301) 594-4648.

Sincerely yours,

Linda S. Kahan
Deputy Director for Regulations and Policy
Center for Devices and Radiological Health

Enclosure: As stated

99P-4132

ANSI

ATTACHMENT 1

MANUFACTURER	MODEL	SERIAL NUMBER
Monad Corporation	MENS 5000i	5K0109
Chattanooga Corporation	Intelect Model 700	3362, 4098, 2343, 2433
EXCEL Tech. Ltd. ~ Ultra Max	Ultra SX	UMX 9607001, UMX 9309040
Physio Technology, Inc.	OmniStim	2279
Medtronic	Respond II Model 3128	Serial number on one unit not available, LM0038713N
Empi	Dupel	516402, 5234545
The Prometheus Group	Pathway MR-20	Not available
Empi	Empix XL	502473, 885996, 7117951
Motion Control	PM 600	4740
Physio Technology, Inc.	OmniStim 3020	1612, 1657
Enraf Nonius Henley International	Sonopuls 434	13-0851
Chattanooga Corporation	Intelect Model 700C 73579	3583, 3678, 2620
Medtronic	Respond II Model PM 600	LM0002419N
Chattanooga Corporation	Intelect	SN2620, SN3557, SN3567
Physio Technology, Inc.	Omnisound 3070C	1548
Physio Technology, Inc.	OmniStim 3010	2502
Mettler Electronics	SYS STIM 206 - ME206	17ST2088
Not available	Neutralizer II	403142, 403146, 402521, 402538, 403148, 564032